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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,278	10/27/2003	Hui Li	S03096/3	9163

7590 12/17/2004

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/695,278

**Applicant(s)**

LI ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 22 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 15-17,25 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 15-17,25 and 32-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Art Unit: 1625

### DETAILED ACTION

1. Applicant's election without traverse of group II in the reply filed on Sept. 22, 2004 is acknowledged.

Preliminary amendment has canceled claims 1-14, 18-24 and 26-31. Claims 15-17, 25, 26-31 are pending.

2. Claims 16-17 recited the limitation "R<sup>3</sup> at the 4-position ...is selected from...." in pages 2-6. There is insufficient antecedent basis for this limitation in the base claim. Please note that the parameter "R<sup>3</sup>" is not found in the base claim but should be incorporated.

Claim 25 recites a species of compound for which no antecedent basis can be found in the specification. There is insufficient antecedent basis for this limitation in the claim.

3. Claims 15 and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and as failing to comply with the enablement requirement under 35 U.S.C. 112, first paragraph,. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The factors to be considered herein are those set forth as the *In re Wands*, 8 USPQ 2<sup>nd</sup> 1400 (1988) decision.

#### Nature of invention

The nature of the invention is a group of new pyrrolidiny compounds having MMP inhibitory activity to be useful in treating diseases.

Art Unit: 1625

*The state of the art and predictability*

The wide variation of MMPs has been well recognized by the art (see Becker Bioorg. Med. Chem.). Small changes in structure would result in tremendous difference in binding activity on the various sub-type of MMP (see p.2725 table 1). In the specification only one pyrrolidinyl compound was exemplified and tested (see example 8).

*The amount of guidance and working examples*

In view of the tremendous unpredictability among the structural close compounds, it was found that the specification is insufficient in description and enablement supporting the claimed scope i.e. all compounds of claim 15 having the same specific selectivity as example 8.

Further, claims 32-34 are reach through claims. Mechanism claims, without end use with explicit nexus between the testing result and the end use clearly described and supported by the specification, are reaching through the future development of the art (see Reach through claims, trilateral project B3b). No documentation was submitted nor found in the specification that the pyrrolidinyl compounds as claimed can be used for any MMP disorder. In addition, it is unclear what is the scope of the term "associated with" is intended since associated with can be inhibiting as well as enhancement for which no description or enablement can be found in the specification. Please note that a compound can be either an inhibitor or an enhancer but can not be simultaneously both as claimed.

4. Claims 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "having a condition associated with matrix metalloproteinase activity" is indefinite and beyond enablement (see rejection supra). It is unclear "what" the condition is since the scope "associated with" encompassed both enhancement and inhibition for which a single compound can not act both way simultaneously.

It is recommended that the particular disorder treatable by the limited tested compound be incorporated into the claims with explicit nexus pointed out in the specification.


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Dec. 6, 2004-12-06*



*Celia Chang*  
*Primary Examiner*  
*Art Unit 1625*